

REMARKS

The present amendment is fully responsive to the Official Action mailed June 5, 2008. A Petition for Revival of an Application for Patent Abandoned Unintentionally Under 37 CFR §1.137(b) accompanies this amendment. This amendment is believed to place the application in condition for allowance at the time of the next Official Action.

Status of the Claims

Claim 16 is amended to define the mutant p53 mediated disease in a manner consistent with claim 17.

Accordingly, claim 17 is cancelled.

Claims 16 and 18 remain in this application.

Claim Rejections-35 USC §112

Claims 16-18 were rejected under 35 U.S.C. §112, first paragraph, for not complying with the enablement requirement. This rejection is respectfully traversed for the reasons below.

The position of the Official Action was that "the scope of the claims include a method for treating cancer in a mammal", and that it was "unclear which type of cancer this drug is going to treat". However, the presently amended claim 16 is clear as to the type of cancer is to be treated. Claim 16 is not directed to simply any cancer. Rather, claim 16 is directed to treating a mutant p53 mediated cancer.

In the application, at pages 1-2, the involvement of mutant p53 in cancer disease is discussed. In fact, at the filing date of the application, it was an established fact that mutant p53 is an important contributing cause in the development of many cancers. In particular, it was well-known that mutant p53 occurs frequently in, for example, cancer of the ovary, colorectum, esophagus, head & neck, larynx, lung and skin. The p53 status of a tumor (wild type or mutant p53) can readily be determined by DNA sequencing. Therefore, one of ordinary skill in the art would have been well enabled to select a mutant p53 mediated cancer for treatment with a compound as defined in the claims.

Moreover, it would be well within the knowledge of the person of ordinary skill in the art to ascertain whether mutant p53 is present or not in a particular cancer patient. Indeed, genetic testing of the required type was well-known already at the filing date of the application. Consequently, it is submitted that one of ordinary skill in the art would have been well enabled to select the cancer that would be treatable by the method as presently claimed.

Furthermore, the present specification at page 19 describes in vivo experiments in mice, and at pages 26 and 27 the specification reports convincing results obtained using PRIMA-1, a close analogue to the presently claimed compounds. The cancer cells implanted and treated in mice were osteosarcoma cells.

At page 27, the specification describes in vitro tests on osteosarcoma and lung adenocarcinoma cell lines containing mutant p53, respectively, using compounds within the scope of present claim 16. These cancer cells, while being of different types, are linked by the fact that they contain mutant p53. The results are shown in the table at pages 8 and 9. It is noted (page 9, lines 23-24) that the tested compounds exhibit a specific activity towards mutant p53 similar to or greater than that of PRIMA-1.

As described at page 27 of the application, the in vitro tests performed also involve the same cell lines, but with null expression of p53, and it is found that in the latter cell lines, the tested compounds have essentially no anti-proliferative effect. Thus, the specificity of the antiproliferative effect of the inventive compounds towards cancer cells containing mutant p53 mediated cancer diseases is shown.

Thus, in view of the above facts and arguments, it is believed that the application does contain an enabling disclosure of a method of treatment of a mutant p53 mediated cancer as presently claimed.

Therefore, withdrawal of the rejection is respectfully requested.

Conclusion

In view of the amendment to the claims and the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our credit card which is being paid online simultaneously herewith for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON

/Robert A. Madsen/
Robert A. Madsen, Reg. No. 58,543
209 Madison Street, Suite 500
Alexandria, VA 22314
Telephone (703) 521-2297
Telefax (703) 685-0573
(703) 979-4709

RAM/jr